

Message Text

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PAGE 01 STATE 125132
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 MED-03 COME-00 /029 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJ'ALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/WE:EJBEIGEL(INFO)

-----312158Z 011799 /14

P 312117Z MAY 77
FM SECSTATE WASHDC
TO AMCONSUL MILAN PRIORITY
INFO AMEMBASSY ROME PRIORITY

UNCLAS STATE 125132

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, IT

SUBJECT: FDA ADVISORY - RECALL T-104-7 DEFECTIVE
(TORN/RIPPED) DIAPHRAGMS

1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE RECALL:

PRODUCT INVOLVED: KORO-FLEX ARCING DIAPHRAGM. SIZE: ALL
SIZES 60MM-95MM. FORM: A VAGINAL DIAPHRAGM: A RESTRICTED
DEVICE TO BE SOLD ONLY BY OR ON THE ORDER OF A PHYSICIAN.
THIS PRODUCT IS INSERT LABELED FOR USE AS A CONTRACEPTIVE
DEVICE WHEN USED WITH A SPERMICIDAL LUBRICANT.

PACKAGING CONFIGURATION: THE PRIMARY UNIT PACKAGE IS A
KIT CONTAINING: 1. KORO-FLEX ARCING DIAPHRAGM (IN SANITARY
PLASTIC CASE), ONE TUBE KOROMEX II VAGINAL JELLY: AND ONE
TUBE KOROMEX II VAGINAL CREAM. THE KOROMEX II VAGINAL
JELLY AND CREAM PRODUCTS ARE LABELED AS CONTRACEPTIVES.
THE PRODUCT LOTS UNDER RECALL WERE ALSO PACKAGED AS IND-
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IVIDUAL DIAPHRAGM UNITS CONSISTING OF ONE DIAPHRAGM IN

THE UNLABELLED PLASTIC CASE, PACKAGED IN A LABELED BOX:
"1 KORO-FLEX MARKING DIAPHRAGM IN SANITARY PLASTIC CASE".

LOT NUMBERS INVOLVED: ONLY LOT NUMBERS F-6, G-6, H-6,
AND I-6 ARE BEING RECALLED. THE LOT NUMBER IS PRINTED

ONLY REPEAT ONLY ON THE RIMS OF THE INDIVIDUAL DIAPHRAGMS.

MANUFACTURER: HOLLAND RANTOS COMPANY, INC.
310 ENTERPRISE AVENUE
TRENTON, NEW JERSEY

RECALLING FIRM: HOLLAND RANTOS COMPANY, INC.
865 CENTENNIAL AVENUE
PISCATAWAY, NEW JERSEY

2. REASON FOR RECALL: SINCE JANUARY 1975, THE FIRM HAS RECEIVED OVER 300 COMPLAINTS FROM CONSUMERS, PHYSICIANS AND PLANNED PARENTHOOD CLINICS. THESE COMPLAINTS REGARD THE APPEARANCE OF "TEARS AND RIPS" IN THE DIAPHRAGM NEAR THE RIM, 2-3 MONTHS AFTER USE. IN ADDITION TO THE SEPARATION OF THE RUBBER DOME AT OR NEAR THE JUNCTURE OF THE RIM OF THE DEVICE APPEARING AS RIPS OR TEARS, IN SOME INSTANCES THE DEFECTS FIRST APPEAR AS PINHOLES. THESE CONDITIONS RENDER THE PRODUCT INEFFECTIVE FOR ITS INTENDED USE AND PURPOSE AS A CONTRACEPTIVE WHEN USED AS DIRECTED ON ITS LABELING WITH A SPERMICIDAL CONTRACEPTIVE CREAM OR JELLY.

3. POST IS REQUESTED TO DETERMINE IF THE FOREIGN CONSIGNEE HAS BEEN NOTIFIED OF THE RECALL TO THE PATIENT/ USER LEVEL IN LETTER DATED 5/5/77. ANY QUESTION FOREIGN CONSIGNEE MAY HAVE WITH REGARD TO THIS RECALL SHOULD BE DIRECTED TO FIRM.

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4. FOREIGN CONSIGNEE AS FOLLOWS:

SANICO SRL.
MILAN, ITALY CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 31-May-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE125132
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770193-0798
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977051/aaaaaawm.tel
Line Count: 101
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: b327c486-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 22-Mar-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2313545
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - RECALL T-104-7 DEFECTIVE (TORN/RIPPED) DIAPHRAGMS
TAGS: OGEN, ETRD, EIND, TBIO, IT
To: MILAN
Type: TE
vdkgvwkey: odhc://SAS/SAS.dbo.SAS_Docs/b327c486-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
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